K042782

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SEP 0 2 2005

Section 2 Summary

510(k) Summary of Safety and Effectiveness

Date: October 4, 2004

Submitter: GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person: Grace LeMieux
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GE Medical Systems Information Technologies
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Device: Trade Name: SEER MC

Common/Usual Name: Holter Recorder

Classification Names: 21 CFR 870.2800 *Electrocardiograph, ambulatory, with analysis algorithm*

Predicate Devices: SEER® (K882818)
Mortara H12+ Holter Recorder (K021373)

Device Description: SEER MC is a Holter Recorder designed to be used in conjunction with an ambulatory ECG system to assist in the diagnosis and assessment of patients. The SEER MC acquires, digitizes, stores and analyzes data for scanning and review by an ambulatory ECG review system. SEER MC can collect and store up to 48 hours of continuous 2 or 3 channels of ambulatory ECG data. In addition, the SEER MC can record and analyze 12 lead ambulatory ECG data periodically or on demand. This analysis performs waveform measurements. These measurements are performed during recording for use in analysis and review within the ambulatory ECG review system.

Intended Use: The SEER MC recorder is intended to provide ambulatory ECG signal and automated analysis of the recorded data. Results of the automated analysis when used in conjunction with an ECG review system are intended to assist the physician in the interpretation of the recorded data. This information is not intended to serve as a substitute for the physician overread of the recorded ECG data. SEER MC can collect and store up to 48 hours of continuous 2 or 3 channels of ambulatory ECG data. In addition, the SEER MC can record and analyze12-lead ambulatory ECG data periodically or on demand. This analysis performs waveform measurements. The SEER MC is intended for use on adult and pediatric (greater than 10Kg) human patients in a clinical setting by qualified medical personnel. Ambulatory ECG monitoring is useful for the following indications:

- Evaluation of symptoms that may be caused by cardiac arrhythmia and/or conduction disturbances
- Evaluation of symptoms that may be due to myocardial ischemia
- Detection of ECG events that alter prognosis in certain forms of heart disease
- Detection and analysis of pacemaker function and failure
- Determination of cardiac response to lifestyle
- Evaluation of therapeutic interventions
- Investigations in epidemiology and clinical trials

SEER MC is not intended to be used as a substitute for a standard, diagnostic-

quality 12-lead electrocardiograph.

Technology: The proposed SEER MC employs the same functional scientific technology as the predicate devices SEER (K882818) and Mortara H12+ (K021373).

Test Summary: The SEER MC complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the device:

- Requirements specification review
- Risk analysis
- Software and hardware testing
- Performance testing
- Safety testing
- Environmental testing
- Clinical use evaluation
- Final validation

Conclusion: The results of these measurements demonstrated that the SEER MC is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 0 2 2005

General Electric Medical Systems Information Technologies
c/o Ms. Lisa M. Baumhardt
Regulatory Affairs Specialist
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K042782
Trade Name: SEER MC Ambulatory Digital Analysis Recorder
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II (two)
Product Code: MLO
Dated: July 6, 2005
Received: July 8, 2005

Dear Ms. Baumhardt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: SEER MC Ambulatory Digital Analysis Recorder

Indications For Use:

The SEER MC Ambulatory Digital Analysis Recorder is intended to provide ambulatory ECG signal and automated analysis of the recorded ECG data. Results of the automated analysis, when used in conjunction with an ECG review system, are intended to assist the physician in the interpretation of the recorded data. This information is not intended to serve as a substitute for the physician overread of the recorded ECG data. The SEER MC can collect and store up to 48 hours of continuous 2 or 3 channels of ambulatory ECG data. In addition, the SEER MC can record and analyze 12-lead ambulatory ECG data for definition of morphology shape and measurements, heart rate, rhythm, and ST segment trending. The SEER MC is intended for use on adult and pediatric (greater than 10Kg) patients in a clinical setting by qualified medical personnel.

The SEER MC in its 2 or 3 channel mode of operation detects the following: normal beats, ventricular beats, supraventricular beats, paced beats and artifact. This information, in conjunction with an ECG review system, documents the following: fastest and slowest heart rate, runs of ventricular beats, runs of supraventricular beats, pauses, ST segment changes, areas of atrial fibrillation, percentage of paced beats, prolonged QT, T-Wave Alternans, Heart Rate Turbulence, Heart Rate Variability and ECG strips associated with patient events and/or symptoms.

The SEER MC in its 12-lead mode of operation, in conjunction with a ECG Review system, documents the aforementioned information and also measures and trends the following 12 lead parameters: PR interval, QT interval, QRS duration, ST measurements at J point plus 40, 60 and 80 mseconds for all 12 leads and displays the Ventricular rate, and P, R and T axis for each 12-lead segment.

The SEER MC is not intended to be used as a substitute for a standard, diagnostic-quality 12-lead electrocardiograph.

Prescription Use__X__ OR Over-The-Counter Use____
(Per 21 CFR 801.109 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

vices
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K042782

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